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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/604,114	06/26/2000	David J. Farrar		3775

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Baker Botts L.L.P.
The Warner, Suite 1300
1299 Pennsylvania avenue, N.W.
Washington, DC 20004-2400

EXAMINER

WOO, JULIAN W

ART UNIT

PAPER NUMBER

3731

DATE MAILED: 06/05/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/604,114

Applicant(s)

FARRAR, DAVID J.

Examiner

Julian W. Woo

Art Unit

3731

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 31 May 2001.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-57 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-6, 12, 13, 15, 16, 18, 19, 21, 22, 24, 25, 27-32, 38-41 and 44-57 is/are rejected.
- 7) ☒ Claim(s) 7-11, 14, 17, 20, 23, 26, 33-37, 42, and 43 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 2.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Claim Objections

1. Claims 12, 30, and 33 are objected to because of informalities, which can be corrected as follows: In claim 12, line 2, "obliqueangle" should be replaced by --oblique angle--. In claim 30, "polyurethane" should be replaced by --polyurethanes--. In claim 33, line 3, "NMI" should be replaced by --MDI--. Appropriate correction is required.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claim 32 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. That is, the term "end-capped with dibutylamine" was not described.

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 15-17, 21, 31, and 40 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In each of base claim 15, claim 21, and claim 40, "said skirt member" lacks antecedent basis. With respect to claim 31, "said polyether urethane-urea" lacks antecedent basis.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) do not apply to the examination of this application as the application being examined was not (1) filed on or after November 29, 2000, or (2) voluntarily published under 35 U.S.C. 122(b). Therefore, this application is examined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

7. Claims 1, 2, 12, 13, 15, 16, 18, 19, 21, and 22 are rejected under 35 U.S.C. 102(b) as being anticipated by Goldberg et al. (3,318,511). With respect to claims 1, 2, 18, 19, 21, and 22, Goldberg et al., in figures 1 and 3, disclose a monolithic graft with a tubular portion (2) and a flared portion (1) with an elongated, circumferential skirt (3), where the central axes of each of the portions are parallel. With respect to claims 12, 13, 15, 16, figure 4 and col. 6, lines 9-14 disclose a flared end with a central axis that is oblique to the central axis of the tubular portion, so that the skirt would be oriented for attachment at an acute angle to a blood vessel.

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8. Claims 1-6, 24, 25, 27-31, 38, 39, and 40 are rejected under 35 U.S.C. 102(e) as being anticipated by Yang et al. (5,989,287). With respect to claims 1-6, 25, 27-31, 39, and 40, Yang et al.; in figures 1B-2B, in col. 5, line 64 to col. 6, line 6, and in col. 6, line 51 to col. 7, line 30, disclose a monolithic, polyurethane graft with a tubular portion (30) and a flared portion (26) with an elliptically-shaped, circumferential skirt (28) or an asymmetrically flared end, where the flared end is oblique to the central axis of the tubular portion, and the skirt is attached at an acute angle to a blood vessel. With respect to claim 24, col. 5, line 66 to col. 6, line 4 disclose a fabric mesh as a reinforcing member.

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

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10. Claims 41 and 44-53 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yang et al. in view of Lyman et al. (4,173,689). Yang et al. disclose a polyurethane graft with a tubular portion and a flared end, but do not disclose a method for manufacturing the graft with a mandrel, the repeated drawing or dipping of the mandrel through polyurethane, and the forming of the shapes of the graft (i.e., masking of portions of the mandrel, controlling the dipping depth, and cutting of graft portions). Lyman et al., in col. 5, line 10 to col. 7, line 2, a method of manufacturing a graft with a mandrel, the repeated drawing or dipping of the mandrel through polyurethane, and the forming of the shapes of the graft. Thus, it would have been obvious to one having ordinary skill in the art at the time the invention was made, in view of Lyman et al., to apply a mandrel, dipping operations with polyurethane, and subsequent cutting of the graft in order to manufacture the graft of Yang et al. Such manufacturing and finishing operations permit the fabrication of grafts of various shapes and forms, including the graft of Yang et al.

11. Claims 54-57 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yang et al. in view of Lyman et al. as applied to claim 41 above, and further in view of Pinchuk et al. (5,116,360). Yang et al. in view of Lyman et al. disclose the invention substantially as claimed, but do not disclose the spraying of polyurethane onto a mandrel in order to form the graft. Pinchuk et al., in col. 2, lines 17-43, teach various methods for forming grafts out of urethanes and a mandrel, including spraying. It would have a matter of design choice to apply spraying techniques as a method for forming at

least portions of the graft of Yang et al. in view of Lyman et al. Such a method would produce a porous graft, if such a graft is desired.

Allowable Subject Matter

12. Claims 7-11, 14, 17, 20, 23, 26, 33-37, 42, and 43 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

13. The following is a statement of reasons for the indication of allowable subject matter: None of the prior art of record, alone or in combination, discloses a graft formed with at least a layer of polyether urethane-urea with an additive having, in a weight range of 1% to 5%, a combination of MDI, polydimethylsiloxane, and 1,4-butanediol. The prior art of record also does not disclose a method of manufacturing a graft with a polyurethane source having by weight, about 600% or about 1400% of sodium chloride with respect to the weight of polymeric solids.

As allowable subject matter has been indicated, applicant's reply must either comply with all formal requirements or specifically traverse each requirement not complied with. See 37 CFR 1.111(b) and MPEP § 707.07(a).

Conclusion

14. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Pinchuk (4,759,757) teach a graft from polymeric solids and sodium chloride. Marcade (5,683,449) teaches a graft with a tubular portion and flared

ends, while Hankh et al. (5,922,019) teach a stent with a tubular portion and a flared end.

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Julian W. Woo whose telephone number is (703) 308-0421. The examiner can normally be reached Mon.-Fri., 7:00 AM to 3:00 PM Eastern Time, alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael J. Milano can be reached at (703) 308-2496.

General inquiries relating to the status of this application should be directed to the Group receptionist at (703)308-0858. The FAX number is (703)872-9302.



Julian W. Woo
Patent Examiner

June 2, 2002